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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,424	04/20/2001	David L. Brown	3364/1 (PHA 4176)	1761

7590 09/02/2004

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EXAMINER

ROBINSON, BINTA M

ART UNIT PAPER NUMBER

1625

DATE MAILED: 09/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,424

Applicant(s)

BROWN ET AL

Examiner

Binta M Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,31,32,35-38,40,41,94,95,101 and 132-137 is/are pending in the application.
- 4a) Of the above claim(s) 132-137 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 7,31,32,35-101 and 115-131 is/are rejected.
- 7) ☒ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Detailed Action

Claims 7, 31-32, 35-38, 40-41, 94-95, 101, 115-122, and 124-137 are pending.

The 112, first paragraph rejection of claims 1-8, 11-16, 31-32, 35-38, 40, 41, 92, 94, 99, 101, 105-113 made at paper no. 8 is withdrawn in light of applicant's remarks at paper dated 5/24/04.

The group I invention drawn to claims 7, 31, 32, 35, 36, 37, 38, 40, 41, 94, 95, 101, 115-122, 124-131, to the compound of formula I where A is thiophene, R1 is phenyl or cyclohexyl optionally substituted as originally claimed, R2 is as claimed, R3 can be all moieties claimed except those containing a heterocycyl ring, a method of treating and a pharmaceutical composition. Claims 132-137 are withdrawn from consideration as not reading on the elected subject matter. The applicant traverses the restriction requirement alleging that the USPTO has not made any showing that the species are independent and distinct and that a burden would be presented on the USPTO to search the entire invention. However, Each Group in the restriction is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may

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be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention.

Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lulu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

In addition, because of the plethora of classes and subclasses in each of the Groups, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application. The applicant alleges that under MPEP 809.02 (e) that whenever a generic claim is found allowable in substance, action on the species claims shall thereupon be given as if the generic claim were allowed. However, this requirement only applies to election of species, not to restriction requirement under 35 USC 121. The restriction is therefore justified and made FINAL.

(new rejections)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 127 -129 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating arthritis in claim 126, does

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not reasonably provide enablement for a method of treating pain, or cancer with the claimed compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

. In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

The nature of the invention is the treatment of cancer, fever, pain, and arthritis with the compounds of formula (I) as found in claim 1.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that cancer therapy remains highly unpredictable. The various types of cancers have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocols. It is known in the prior art cyclooxygenase in tumor biology. Cyclooxygenase inhibitors have been established in the art to be used for low to moderate intensity pain, and high intensity pain. (See Ca 140:228152) but not all types of pain. The Cyclooxygenase inhibitor, Celecoxib has

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been shown to achieve analgesic and anti-inflammatory efficacy in arthritis. (See Ca 130:320290).

Cyclo-oxygenase inhibitors may have important therapeutic relevance in the treatment of some cancers but not all of them. (See 132:73082). Cox-3 inhibitor, paracetamol, known to treat inflammation and pain, is not known to treat fever. See Ca 13:270087.

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present in the instant specification is found on 14 when cyclooxygenase -2- is said to be selectively inhibited by these compounds over cyclooxygenase 1.

The breadth of the claims

The breadth of the claims is the treatment of all cancers, fever, and all pain.

The quantity of experimentation needed

The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to all cancers, to the treatment of fever and the treatment of all types of pain and when faced with the unpredictability of the cancer therapy art.

The level of the skill in the art

Even though the level of skill in the cancer therapy art is very high, based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims and lack of guidance and direction for the treatment of all cancers, all

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types of pain, and fever, one skilled in the art could not use the claimed invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 125-128 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 125 recites the limitation "inflammation-associated disorder" in line 2, page 21. There is insufficient antecedent basis for this limitation in the claim.

B. Claims 126-128 recites the limitation "inflammation-associated disorder" which are arthritis, pain, and fever in claims 126-128 respectively. There is insufficient antecedent basis for this limitation in the claim.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 7, 31-32, 35-38, 40-41, 94-95, 98, 115-122, 124-131 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16, 32-42, 83-89, 92, 94, 96, 98, 101, 104-106 of U.S. Patent No. 6673818. Although the conflicting claims are not identical, they are not patentably distinct from each other because the US Patent claims a genus that encompasses the instant subgenus of compounds, as well as a pharmaceutical composition, and a method of treating inflammation with these compounds.

U.S. Patent No. 6673818 teaches the instant compound as shown in Formula I, where A is a 5- or 6-membered ring selected from partially saturated or unsaturated heterocyclic and carbocyclic rings, X is fluoro, n is an integer greater than or equal to 2, R₁ is cyclohexyl, pyridinyl, or phenyl wherein said cyclohexyl, pyridinyl, and phenyl may be optionally substituted with one, two or three radicals selected from C₁-2alkyl, C₁-2haloalkyl, cyano, carboxyl, C₁-2 alkoxycarbonyl, hydroxy, C₁-2hydroxyalkyl, C₁-2 haloalkoxy, amino, C₁-2 alkylamino, phenylamino, nitro, C₁-2 alkoxycarbonyl, C₁-2alkylsulfinyl, halo, C₁-2 alkoxy and C₁-3alkylthio, R₂ is alkyl or amino, and R₃ represent one or more radicals selected from all of the radicals named at column 182. The difference between the prior art compound, composition, and method of treating inflammation and the instantly claimed compounds, composition, and method of treating inflammation is the teaching of a genus versus a subgenus of compounds. It would have been obvious to one of ordinary skill in the art to select various known radicals within a genus to prepare structurally similar compounds. For instance, see the compound, 5-phenyl -1-[3,5-difluoro-4-(methylsulfonyl)phenyl]-3-(trifluoromethyl)-1H-

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pyrazole , where a disclosed species is exemplified. Accordingly, the compounds, compositions and method of treating are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

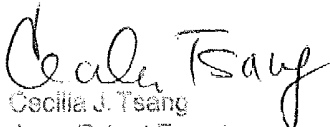
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.

BMR
August 9, 2004


Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600